

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015 (LPS)
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	

JOINT STATUS REPORT

I. NIPPON SHINYAKU'S STATEMENT

A. Procedural Background. On December 10, 2021 (D.I. 81, Order), the Court denied Nippon Shinyaku Co., Ltd.'s ("NS") request to compel Sarepta Therapeutics, Inc. ("Sarepta") to attend a Rule 26(f) conference and commence discovery in this case. However, the Court agreed to reconsider the request in view of the pending matters: 1) Sarepta's motion to dismiss and strike select aspects of NS's First Amended Complaint, 2) the Federal Circuit argument on NS's interlocutory appeal of the denial of the preliminary injunction against Sarepta's IPR petitions, and 3) PTAB institution decisions on Sarepta's *inter partes* review petitions." *Id.* Since the Order, the motion to dismiss has been resolved, with the Court granting the motion in part and denying the motion to dismiss NS's declaratory judgment claim of invalidity of Sarepta's patents.¹ D.I. 85. The Federal Circuit heard oral argument on January 11, 2022. While NS remains confident in its position regarding contract interpretation of the forum selection clause and has requested an expedited ruling, the date the opinion will issue is uncertain. Finally, the PTAB has instituted Sarepta's IPRs directed to the asserted NS patents.

B. NS's renewed request for a Rule 26 conference. As the Court acknowledged, no rule provides that a party may unilaterally delay a Rule 26(f) conference. D.I. 81. This case has been pending for over *six months*, and NS has been unable to proceed with discovery. Meanwhile, discovery is permitted to proceed in Sarepta's pending IPRs. Thus, there is no reason to preclude discovery because neither the IPRs nor the Federal Circuit appeal will resolve all claims at issue in this case. First, NS's declaratory judgment of invalidity of Sarepta's patents (now Claim II) is *unrelated* to the issues before the Federal Circuit and PTAB. NS continues to be prejudiced in not being able to advance this claim to secure freedom to operate given there has been found to be "a substantial controversy of sufficient immediacy and reality to warrant the issue of a declaratory judgment" related to Sarepta's patents. D.I. 85 at 38:4-8. Second, uncertainty about the timing and scope of the Federal Circuit's ruling should not delay discovery NS's breach of contract claim (Claim I). This presents an issue as to the *scope* of discovery that the parties can address when the opinion issues, if needed. Although Sarepta intends to pursue a stay of NS's infringement claims (now Claims III-IX) due to the pending IPR proceedings, these claims remain in force until Sarepta moves for *and* is granted a stay, which has not occurred, and any motion may not be resolved for several months.² If infringement discovery cannot move forward during the time before resolution of any motion to stay, this will further prejudice NS's right to timely pursue these claims in this forum. Accordingly, NS respectfully requests that the Court order the parties to hold a Rule 26(f) conference on or before February 4, 2022, which is seven days after Sarepta must file its response to NS's complaint.

¹ NS's original Claims I (breach of contract) and IV-X (NS's infringement claims) were not subject to the motion to dismiss. NS has filed its Second Amended Complaint. D.I. 86. In order to ensure that this case can promptly move forward (and eliminate another basis for Sarepta to delay), NS will proceed on the claims therein and reserves the right to plead the defense of non-infringement in response to a Sarepta claim of infringement.

² NS will oppose any forthcoming motion to stay because, *inter alia*, it would be inappropriate to stay the *entire* case because the IPRs pertain only to NS's patents and could not impact NS's breach of contract claim and invalidity assertions against Sarepta's patents.

II. SAREPTA’S STATEMENT ON THE NATURE OF THE MATTERS IN ISSUE

A. Pleadings

Nippon Shinyaku filed its Second Amended Complaint (SAC) last Friday, January 14, 2022. The SAC omits confidential material the Court struck from the First Amended Complaint on December 20, 2021. In addition, the SAC does not assert a claim for declaratory judgment of non-infringement of UWA Patents licensed to Sarepta (previously Claim II of the First Amended Complaint), which was asserted in the First Amended Complaint. Sarepta’s response to the SAC is due by January 28, 2022.

B. Sarepta’s IPR Petitions

The PTAB has granted institution of all seven of Sarepta’s IPR petitions challenging the Nippon Shinyaku patents asserted in this case, finding in each proceeding that Sarepta “has demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable.”³ The instituted IPR proceedings will address the patentability of *all* claims of all seven Nippon Shinyaku patents at issue in this case. The PTAB has entered Scheduling Orders in the instituted IPRs, including an October 4, 2022 oral argument date. The PTAB’s final written decisions are due no later than one year after the institution decisions.

C. Potential Stay

In view of the grants of Sarepta’s IPR petitions and the early stage of this case, Sarepta is seeking Nippon Shinyaku’s agreement to stay this case or, alternatively, to stay Nippon Shinyaku’s infringement claims until entry of the PTAB’s last final written decision. Sarepta intends to move promptly for a stay (or partial stay) of this case through issuance of the PTAB’s last final written decision.

D. Federal Circuit Appeal

The Federal Circuit held oral argument on January 11, 2022 in connection with Nippon Shinyaku’s interlocutory appeal from this Court’s denial of its preliminary injunction motion. The Federal Circuit has not yet issued a decision.

E. Nippon Shinyaku’s Request for a Rule 26(f) Conference

In order to promote efficiency and conserve the resources of the Court and the parties, Sarepta believes that it would be appropriate to resolve the question of a stay (or partial stay) of this case before a Rule 26(f) conference is scheduled. In addition, Sarepta believes that the scope of the issues to be litigated in this case will be more clearly defined after Sarepta responds to Nippon Shinyaku’s SAC.

³ See *Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134; IPR2021-01135; IPR2021-01136; IPR2021-01137; IPR2021-01138; IPR2021-01139; IPR2021-01140.

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